



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172, 173, 178, and 180

[Docket No. FDA-2010-F-0320]

Food Additive Regulations; Incorporation by Reference of the Food Chemicals Codex, 7th Edition

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending select food additive regulations that incorporate by reference food-grade specifications from prior editions of the Food Chemicals Codex (FCC) to incorporate by reference food-grade specifications from the FCC 7th Edition (FCC 7). We are taking this action in response to a petition filed by the United States Pharmacopeial Convention (U.S.P. or petitioner).

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See the “Objections” heading of the SUPPLEMENTARY INFORMATION section for information on the filing of objections. Submit either electronic or written objections and requests for a hearing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications listed in the rule as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA-2010-F-0320, by any of the following methods:

### Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

### Written Submissions

Submit written objections in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2010-F-0320 for this rulemaking. All objections received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting objections, see the “Objections” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mical Honigfort, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1278.

SUPPLEMENTARY INFORMATION:

## I. Background

In a notice published in the Federal Register of August 10, 2010 (75 FR 48353), we announced that the U.S.P., 12601 Twinbrook Pkwy., Rockville, MD 20852, had filed a food additive petition. The petition proposed that select food additive regulations in parts 172, 173, 178, and 180 (21 CFR parts 172, 173, 178, and 180), which incorporate by reference food-grade specifications from prior editions of the FCC, be amended to incorporate by reference food-grade specifications from FCC 7.

The FCC is a compendium of specification monographs for substances used as food ingredients. The Committee on Food Chemicals Codex of the Food and Nutrition Board, Institute of Medicine (IOM) of the National Academies published the first through fifth editions of the FCC. In 2006, U.S.P. acquired the rights to the FCC, and subsequently published the sixth, seventh, and eighth editions. Specifications and methods published in the FCC have been incorporated by reference in various sections of 21 CFR parts 73, 170, 172, 173, 178, 180, and 184.

Since acquiring rights to the FCC, U.S.P. has developed and continues to develop standards for food ingredients through public participation with a goal of biennial publication of the FCC. Draft monographs and data are provided by food ingredient manufacturers, users, and suppliers and are published for public review and comment on U.S.P.'s Web site. U.S.P. scientists and its Food Ingredients Expert Committee review these data and, if necessary, conduct laboratory tests. Once approved by the Food Ingredients Expert Committee, new or updated monographs are published in the next edition or Supplement to the FCC.

The petitioner initially requested amendments to 39 existing references to older editions of the FCC in parts 172, 173, 178, and 180 to incorporate by reference the specifications contained in FCC 7. The petitioner explained that of the regulations it has requested to be

updated, 15 regulations refer to the third edition of the FCC (FCC III, published in 1981); 18 regulations refer to the fourth edition of the FCC (FCC IV, published in 1996); 4 regulations refer to the fifth edition of the FCC (FCC V, published in 2004); and 2 regulations refer to the sixth edition of the FCC (FCC 6, published in 2008). (The IOM used roman numerals when referring to editions of the FCC, e.g., FCC III and FCC V. U.S.P. uses numbers rather than roman numerals to refer to the editions of FCC that it has published, e.g., FCC 6 and FCC 7.) In most cases, the references to the FCC in the regulations are to an entire FCC monograph. Some references, however, only refer to part of an FCC monograph, i.e., a single specification, or to an FCC analytical method.

After discussions with us in July 2011, the petitioner subsequently narrowed its petition to exclude six regulations ((§§ 172.172.723(b)(3), 172.833(b)(4), 172.846(b), 172.858(a), 180.25(b), and 180.30(a)). The current regulation for epoxidized soybean oil (§ 172.723(b)(3)) includes a limit of 10 milligrams per kilogram (mg/kg) for heavy metals (as lead (Pb)), as determined by Method II of the “Heavy Metals Test” in FCC IV. FCC 7, however, does not include a monograph for epoxidized soybean oil and does not include the “Heavy Metals Test” as a general test in the appendices of FCC 7. Accordingly, § 172.723(b)(3) has been excluded from the petition. U.S.P. has excluded the remaining five regulations (§§ 172.833(b)(4), 172.846(b), 172.858(a), 180.25(b), and 180.30(a)) based on its need to further investigate the bases for such updates.

The petitioner cited several reasons for updating the references to older editions of the FCC to specifications and analytical methodologies contained in FCC 7. First, previous editions of the FCC are no longer readily available to industry or the public, since U.S.P. does not maintain and therefore cannot provide copies of monographs from FCC III, IV, or V to industry

or the public. (Under 5 U.S.C. 552(a) and 1 CFR 51.7(a)(4), a publication that is to be incorporated by reference must be “reasonably available” to and capable of being used by persons affected by the publication.) Second, the petitioner maintained that updating the references to older editions of the FCC to FCC 7 may avoid confusion, inconsistency, and lack of uniformity in the quality of food additives and ingredients manufactured and sold. Third, the petitioner noted that, in many cases, the editions of the FCC prior to FCC 7 may employ outdated analytical methodologies and equipment that do not reflect current scientific practices, and which may be difficult to obtain.

We note that, subsequent to our analysis of FCC 7, the U.S.P. published the eighth edition of the FCC (FCC 8) in March 2012. Initiating a review of FCC 8 at this time would delay issuance of this final rule. To avoid a delay in updating the references to the FCC in our food additive regulations, we are proceeding with issuing this final rule to incorporate by reference FCC 7. The specific food additive regulations explain how to obtain copies of FCC 7. As appropriate, we will provide further updates to our food additive regulations to reflect more recent versions of the FCC.

## II. Evaluation of Amendments to Parts 172, 173, 178, and 180

We compared the specifications and analytical methods in the versions of the FCC currently referenced in the regulations to the specifications and analytical methods in FCC 7 (Ref. 1). In addition, we note that some general changes were made to FCC monographs published in or after FCC IV that remain in FCC 7. One change is that the older FCC monographs discussed in this document that contain a specification limit for heavy metals (as Pb) were updated in FCC V to remove this specification, and, when appropriate, to replace it with an individual specification limit for each relevant heavy metal. Many FCC 7 monographs

have also adopted lower lead limit specifications compared to earlier FCC editions, to reduce lead in food. Furthermore, if an earlier edition of the FCC contained a specification limit for arsenic, that specification has been removed unless the monograph met one of the following criteria: (1) The ingredient or additive is a high-volume consumption item (greater than 25 million pounds per year), (2) the ingredient or additive is derived from a natural (mineral) source where arsenic may be an intrinsic contaminant, and/or (3) there is reason to believe that arsenic constitutes a significant part of the total heavy metals content (Ref. 1).

An FCC monograph typically consists of a description of the substance, its functional use, the recommended specifications for the substance, and testing methodology. In many cases, there are minor differences between the description or functional use of a substance provided in FCC 7 compared to the description or functional use of a substance provided in earlier editions of the FCC and the CFR. However, FCC 7 provides the description and functional use of a substance specified in a monograph for informational purposes, e.g., to help industry understand the possible functions of the ingredients, rather than as a required standard. Other differences (e.g., solvent or instrument changes) between the specifications and analytical methods in the version of the FCC currently referenced in the regulations and the specifications and analytical methods in FCC 7 are discussed further in the FDA Memoranda from D. Folmer to M. Honigfort (Refs. 1 through 3).

After review of each proposed amendment, we are updating the regulations shown in table 1 to incorporate FCC 7 by reference. We note that the safety of these additives has been previously considered and there are no safety concerns with the proposed changes to incorporate by reference the specifications and analytical methodologies contained in FCC 7. We are also amending § 178.1005 to incorporate by reference the specifications for “Acidity,” “Chloride”

and “Other requirements” for Hydrogen Peroxide Concentrate in the United States Pharmacopeia, 36th Revision (2013). This updates the reference to the United States Pharmacopeia XX (1980) already cited in § 178.1005. We compared the United States Pharmacopeia XX (1980) monograph for Hydrogen Peroxide Concentrate to the United States Pharmacopeia, 36th Revision (2013) monograph for Hydrogen Peroxide Concentrate and determined that this update is safe and appropriate (Ref. 4).

Table 1.--List of Regulations

21 CFR Section	Name of Additive	FCC 7 Reference
172.167(b)	Hydrogen peroxide	Meets FCC 7 specifications
172.320(b)(1)	Amino acids	Meets FCC 7 specifications
172.345(b)	Folic acid (folacin)	Meets FCC 7 specifications
172.379(b)	Vitamin D <sub>2</sub>	Meets FCC 7 specifications
172.380(b)	Vitamin D <sub>3</sub>	Meets FCC 7 specifications
172.665(d)(2)	Gellan gum	Residual isopropyl alcohol limit not to exceed 0.075% by the procedure described in the Gellan Gum monograph in FCC 7
172.712(b)	1,3-Butylene glycol	Conforms to FCC 7 identity and specifications
172.736(b)(2)	Glycerides and polyglycides of hydrogenated vegetable oils	Acid value not greater than 2, and hydroxyl value, not greater than 56 as determined by “Acid Value” and “Hydroxyl Value” methods
172.780(b)	Acacia (gum arabic)	Meets FCC 7 specifications
172.800(b)(2)	Acesulfame potassium	Fluoride content not more than 30 milligrams per kilogram (mg/kg) as determined by Method III of the Fluoride Limit Test (We have amended the specification for fluoride content in acesulfame potassium in § 172.800(b)(2) to replace “parts per million” with “mg/kg” to be consistent with terminology used elsewhere in the regulations cited in this rule.)
172.804(b)	Aspartame	Meets FCC 7 specifications
172.810	Diocetyl sodium sulfosuccinate	Meets FCC 7 specifications
172.812(a)	Glycine	Meets FCC 7 specifications
172.831(b)	Sucralose	Meets FCC 7 specifications
172.841(b)	Polydextrose	Meets FCC 7 specifications
172.862(b)(1)	Oleic acid derived from tall oil fatty acids	Meets FCC 7 specifications except that titer (solidification point) shall not exceed 13.5 degrees Celsius and unsaponifiable matter shall not exceed 0.5%

Table 1.--List of Regulations

21 CFR Section	Name of Additive	FCC 7 Reference
172.867(b)	Olestra	Meets FCC 7 specifications
172.869(b)(6)	Sucrose oligoesters	Acid value not more than 4.0 as determined by the method "Acid Value," Appendix VII, Method I (Commercial Fatty Acids)
172.869(b)(7)	Sucrose oligoesters	Residue on ignition not more than 0.7% as determined by "Residue on Ignition," Appendix IIC, Method I (using a 1 gram sample)
172.869(b)(8)	Sucrose oligoesters	Residual methanol not more than 10 mg/kg as determined by the method listed in the monograph for "Sucrose Fatty Acid Esters"
172.869(b)(9)	Sucrose oligoesters	Residual dimethyl sulfoxide not more than 2.0 mg/kg as determined by the method listed in the monograph "Sucrose Fatty Acid Esters"
172.869(b)(10)	Sucrose oligoesters	Residual isobutyl alcohol not more than 10 mg/kg as determined by the method listed in the monograph "Sucrose Fatty Acid Esters"
172.869(b)(11)	Sucrose oligoesters	Lead not more than 1.0 mg/kg as determined by "Atomic Absorption Spectrophotometric Graphite Furnace Method," Method I
173.160(d)	<u>Candida guilliermondii</u>	Citric acid produced must conform to FCC 7 specifications (under "Citric acid")
173.165(d)	<u>Candida lipolytica</u>	Citric acid produced must conform to FCC 7 specifications (under "Citric acid")
173.228(a)	Ethyl acetate	Meets FCC 7 specifications
173.280(c)	Solvent extraction process for citric acid	Citric acid produced must conform to FCC 7 specifications (under "Citric acid")
173.310(c)	Boiler water additives; Sodium carboxymethylcellulose	Contains not less than 95% sodium carboxymethylcellulose on a dry-weight basis, with maximum substitution of 0.9 carboxymethylcellulose groups per anhydroglucose unit, and with a minimum viscosity of 15 centipoises for 2% by weight aqueous determined by the "Viscosity of Cellulose Gum" method cited in FCC 7
173.310(c)	Boiler water additives; Sorbitol anhydride esters	Polysorbate 20 present in sorbitol anhydride esters meets FCC 7 specifications (We have amended the limitation for sorbitol anhydride esters in § 173.310(c) to replace "parts per million" with "mg/kg" to be consistent with terminology used elsewhere in the regulations cited in this rule.)
173.368(c)	Ozone	Meets FCC 7 specifications
178.1005(c)	Hydrogen peroxide solution	Meets FCC 7 specifications (We are also amending the regulation to incorporate by reference the United States Pharmacopeia, 36th Revision.)
180.37(b)	Saccharin, ammonium	Meets FCC 7 specifications



Table 1.--List of Regulations

21 CFR Section	Name of Additive	FCC 7 Reference
	saccharin, calcium saccharin, and sodium saccharin	

The petitioner also requested amending § 173.115(b)(3) (Alpha-acetolactate decarboxylase ( $\alpha$ -ALDC) enzyme preparation derived from a recombinant Bacillus subtilis).

The current regulation requires that the enzyme preparation should meet the general and additional requirements for enzyme preparations found in FCC IV. FCC 7 specifically includes  $\alpha$ -ALDC in the list of enzyme preparations, but does not contain an assay method specific to  $\alpha$ -ALDC. We are not amending § 173.115(b)(3) at this time to incorporate by reference the specifications in FCC 7 because the assay method for  $\alpha$ -ALDC has been omitted from FCC 7.

Additionally, on our own initiative, we are amending certain provisions in parts 172, 173, 178, and 180 to update the address at which copies of FCC 7 can be examined. In most cases, the existing regulations refer to an FDA address at “5100 Paint Branch Pkwy., College Park, MD 20740.” However, in 2013, we consolidated our library holdings at our main library at 10903 New Hampshire Ave., Silver Spring, MD 20993. Therefore, we are amending various provisions to reflect the current FDA address at which copies of FCC 7 can be examined.

### III. Conclusion

We reviewed data in the petition and other relevant material and conclude that the proposed amendments to the regulations listed in table 1 to incorporate by reference food-grade specifications and analytical methodologies from FCC 7, as discussed in Section II of this document, are safe and appropriate. Therefore, we are amending parts 172, 173, 178, and 180 as set forth in this document.

### IV. Public Availability of Documents

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

#### V. Environmental Impact

Under part H in § 171.1(c), either an environmental assessment under 21 CFR 25.40 or a claim of categorical exclusion under § 25.30 (21 CFR 25.30) or § 25.32 (21 CFR 25.32) is required to be submitted with a food additive petition. As initially filed by U.S.P., the petition contained a claim of categorical exclusion under § 25.30(i), which applies to corrections and technical changes in regulations. We reviewed the petitioner's claim of categorical exclusion and stated in our original filing notice of August 10, 2010, that we agreed that, under § 25.30(i), the proposed action was of a type that would not individually or cumulatively have a significant effect on the human environment and therefore that neither an environmental assessment nor an environmental impact statement would be required.

However, upon further review, we decided that as a group, the actions being requested are neither corrections nor technical changes and therefore the categorical exclusion in § 25.30(i) would not be applicable. Accordingly we announced, in an amended filing notice published in the Federal Register of January 18, 2012 (77 FR 2492), that U.S.P. had submitted an environmental assessment for the petition in lieu of a claim of categorical exclusion and that we would review the potential environmental impact of the petition. We placed the petitioner's environmental assessment on display in the Division of Dockets Management for public review and comment.

We have carefully reviewed the environmental assessment and considered the potential environmental effects of this action. We have concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. Our finding of no significant impact and the evidence supporting that finding, contained in the environmental assessment, may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

#### VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### VII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection. It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in

the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

#### VIII. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

Our review of this petition was limited to section 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348). This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)). Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exceptions in section 301(ll)(1) to (ll)(4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing these additives. Accordingly, this final rule should not be construed to be a statement that a food containing these additives, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

#### IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. FDA Memorandum from D. Folmer to M. Honigfort, October 24, 2011.
2. FDA Memorandum from D. Folmer to M. Honigfort, February 8, 2013.
3. FDA Memorandum from D. Folmer to M. Honigfort, February 27, 2013.
4. FDA Memorandum from D. Folmer to M. Honigfort, October 31, 2013.

#### List of Subjects

##### 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

##### 21 CFR Part 173

Food additives, Incorporation by reference.

##### 21 CFR Part 178

Food additives, Food packaging, Incorporation by reference.

##### 21 CFR Part 180

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR parts 172, 173, 178, and 180 are amended as follows:

#### **PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION**

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Amend § 172.167 by revising paragraph (b) to read as follows:

§ 172.167 Silver nitrate and hydrogen peroxide solution.

\* \* \* \* \*

(b) Hydrogen peroxide meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 496-497, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

3. Revise § 172.320 to read as follows:

§ 172.320 Amino acids.

The food additive amino acids may be safely used as nutrients added to foods in accordance with the following conditions:

(a) The food additive consists of one or more of the following individual amino acids in the free, hydrated, or anhydrous form, or as the hydrochloride, sodium, or potassium salts:

(1) L-Alanine

(2) L-Arginine

- (3) L-Asparagine
- (4) L-Aspartic acid
- (5) L-Cysteine
- (6) L-Cystine
- (7) L-Glutamic acid
- (8) L-Glutamine
- (9) Aminoacetic acid (glycine)
- (10) L-Histidine
- (11) L-Isoleucine
- (12) L-Leucine
- (13) L-Lysine
- (14) DL-Methionine (not for infant foods)
- (15) L-Methionine
- (16) L-Phenylalanine
- (17) L-Proline
- (18) L-Serine
- (19) L-Threonine
- (20) L-Tryptophan
- (21) L-Tyrosine
- (22) L-Valine

(b) The food additive meets the following specifications:

(1) As found in Food Chemicals Codex:

(i) L-Alanine, pages 28 and 29.

- (ii) L-Arginine, pages 69 and 70.
- (iii) L-Arginine Monohydrochloride, pages 70 and 71.
- (iv) L-Cysteine Monohydrochloride, pages 269 and 270.
- (v) L-Cystine, pages 270 and 271.
- (vi) Aminoacetic acid (glycine), pages 457 and 458.
- (vii) L-Leucine, pages 577 and 578.
- (viii) DL-Methionine, pages 641 and 642.
- (ix) L-Methionine, pages 642 and 643.
- (x) L-Tryptophan, pages 1060 and 1061.
- (xi) L-Phenylalanine, pages 794 and 795.
- (xii) L-Proline, pages 864 and 865.
- (xiii) L-Serine, pages 915 and 916.
- (xiv) L-Threonine, pages 1031 and 1032.
- (xv) L-Glutamic Acid Hydrochloride, page 440.
- (xvi) L-Isoleucine, pages 544 and 545.
- (xvii) L-Lysine Monohydrochloride, pages 598 and 599.
- (xviii) Monopotassium L-glutamate, pages 697 and 698.
- (xix) L-Tyrosine, page 1061.
- (xx) L-Valine, pages 1072.

(2) As found in “Specifications and Criteria for Biochemical Compounds,” NAS/NRC Publication, for the following:

- (i) L-Asparagine
- (ii) L-Aspartic acid



(iii) L-Glutamine

(iv) L-Histidine

(c) The additive(s) is used or intended for use to significantly improve the biological quality of the total protein in a food containing naturally occurring primarily intact protein that is considered a significant dietary protein source, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact protein (based upon 10 percent of the daily allowance for the “reference” adult male recommended by the National Academy of Sciences in “Recommended Dietary Allowances,” NAS Publication No. 1694.

(2) The additive(s) results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.

(3) Each amino acid (or combination of the minimum number necessary to achieve a statistically significant increase) added results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the amino acid(s) to achieve the desired effect must be used and the increase in PER over the primarily intact naturally occurring protein in the food must be substantiated as a statistically significant difference with at least a probability (P) value of less than 0.05.

(4) The amount of the additive added for nutritive purposes plus the amount naturally present in free and combined (as protein) form does not exceed the following levels of amino acids expressed as percent by weight of the total protein of the finished food:

	Percent by weight of total protein (expressed as free amino acid)
L-Alanine	6.1
L-Arginine	6.6
L-Aspartic acid (including L-asparagine)	7.0
L-Cystine (including L-cysteine)	2.3
L-Glutamic acid (including L-glutamine)	12.4
Aminoacetic acid (glycine)	3.5
L-Histidine	2.4
L-Isoleucine	6.6
L-Leucine	8.8
L-Lysine	6.4
L- and DL-Methionine	3.1
L-Phenylalanine	5.8
L-Proline	4.2
L-Serine	8.4
L-Threonine	5.0
L-Tryptophan	1.6
L-Tyrosine	4.3
L-Valine	7.4

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in sections 43.212-43.216, “Official Methods of Analysis of the Association of Official Analytical Chemists.” Each manufacturer or person employing the additive(s) under the provisions of this section shall keep and maintain throughout the period of his use of the additive(s) and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and

compliance with this regulation and shall make such records available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration, or any other officer or employee acting on behalf of the Secretary of Health and Human Services and shall permit such officer or employee to conduct such inventories of raw and finished materials on hand as he deems necessary and otherwise to check the correctness of such records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The name of the amino acid(s) contained therein including the specific optical and chemical form.

(2) The amounts of each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) The food additive amino acids added as nutrients to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and comply with the requirements of part 105 of this chapter are exempt from the limitations in paragraphs (c) and (d) of this section and may be used in such foods at levels not to exceed good manufacturing practices.

(g) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of

this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(1) AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877:

(i) Sections 43.212-43.216, "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980).

(ii) [Reserved].

(2) National Academy of Sciences, available from the FDA Main Library, 10903 New Hampshire Ave., Silver Spring, MD 20993:

(i) "Recommended Dietary Allowances," NAS Publication No. 1694, 7th Ed. (1968).

(ii) "Specifications and Criteria for Biochemical Compounds," NAS/NRC Publication, 3rd Ed. (1972).

(3) United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>):

(i) Food Chemicals Codex, 7th ed. (2010), pages 28, 29, 69, 70, 71, 269, 270, 271, 440, 457, 458, 544, 545, 577, 578, 598, 599, 641, 642, 643, 697, 698, 794, 795, 864, 865, 915, 916, 1031, 1032, 1060, 1061, and 1072.

(ii) [Reserved].

4. Amend § 172.345 by revising paragraph (b) to read as follows:

§ 172.345 Folic acid (folacin).

\* \* \* \* \*

(b) Folic acid meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 406-407, which is incorporated by reference. The Director of the Office of the Federal Register

approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

5. Amend § 172.379 by revising paragraph (b) to read as follows:

§ 172.379 Vitamin D<sub>2</sub>

\* \* \* \* \*

(b) Vitamin D<sub>2</sub> meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 1080-1081, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

6. Amend § 172.380 by revising paragraph (b) to read as follows:

§ 172.380 Vitamin D<sub>3</sub>.

\* \* \* \* \*

(b) Vitamin D<sub>3</sub> meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 1081-1082, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

7. Amend § 172.665 by revising paragraph (d)(2) to read as follows:

§ 172.665 Gellan gum.

\* \* \* \* \*

(d) \* \* \*

(2) Residual isopropyl alcohol (IPA) not to exceed 0.075 percent as determined by the procedure described in the "Gellan gum" monograph in the Food Chemicals Codex, 7th ed. (2010), pp. 425-426, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives

and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

8. Amend § 172.712 by revising paragraph (b) to read as follows:

§ 172.712 1,3-Butylene glycol.

\* \* \* \* \*

(b) The food additive shall conform to the identity and specifications of the Food Chemicals Codex, 7th ed. (2010), p. 126, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

9. Amend § 172.736 by revising paragraph (b)(2) to read as follows:

§ 172.736 Glycerides and polyglycides of hydrogenated vegetable oils.

\* \* \* \* \*

(b) \* \* \*

(2) Acid value, not greater than 2, and hydroxyl value, not greater than 56, as determined by the methods entitled “Acid Value,” p. 1220 and “Hydroxyl Value,” p. 1223, respectively, in the Food Chemicals Codex, 7th ed. (2010), which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to:

<http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

10. Amend § 172.780 by revising paragraph (b) to read as follows:

§ 172.780 Acacia (gum arabic).

\* \* \* \* \*

(b) The ingredient meets the specifications of the Food Chemicals Codex, 7th ed. (2010), p. 460, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records



Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

11. Amend § 172.800 by revising paragraph (b)(2) to read as follows:

§ 172.800 Acesulfame potassium.

\* \* \* \* \*

(b) \* \* \*

(2) Fluoride content is not more than 30 milligrams per kilogram, as determined by method III of the Fluoride Limit Test of the Food Chemicals Codex, 7th ed. (2010), p. 1151, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

12. Amend § 172.804 by revising paragraph (b) to read as follows:

§ 172.804 Aspartame.

\* \* \* \* \*

(b) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 73-74, which is incorporated by reference. The Director of the Office of the Federal Register

approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

13. Revise the introductory text of § 172.810 to read as follows:

§ 172.810 Dioctyl sodium sulfosuccinate.

The food additive, dioctyl sodium sulfosuccinate, meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 313-314, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>). The food additive, dioctyl sodium sulfosuccinate, may be safely used in food in accordance with the following prescribed conditions:

\* \* \* \* \*

14. Amend § 172.812 by revising paragraph (a) to read as follows:

§ 172.812 Glycine.

\* \* \* \* \*

(a) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 457-458, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

15. Amend § 172.831 by revising paragraph (b) to read as follows:

§ 172.831 Sucralose.

\* \* \* \* \*

(b) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 993-995, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and

Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

16. Amend § 172.841 by revising paragraph (b) to read as follows:

§ 172.841 Polydextrose.

\* \* \* \* \*

(b) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 811-814, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

17. Amend § 172.862 by revising paragraph (b)(1) to read as follows:

§ 172.862 Oleic acid derived from tall oil fatty acids.

\* \* \* \* \*

(b) \* \* \*

(1) Specifications for oleic acid prescribed in the Food Chemicals Codex, 7th ed. (2010), pp. 743-744, which is incorporated by reference, except that titer (solidification point) shall not exceed 13.5 °C and unsaponifiable matter shall not exceed 0.5 percent. The Director of the

Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

18. Amend § 172.867 by revising paragraph (b) to read as follows:

§ 172.867 Olestra.

\* \* \* \* \*

(b) Olestra meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 744-746, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

19. Amend § 172.869 by revising paragraph (b) introductory text and paragraphs (b)(6) through (b)(11) to read as follows:

§ 172.869 Sucrose oligoesters.

\* \* \* \* \*

(b) Sucrose oligoesters meet the specifications in the methods listed in the table in this paragraph. The methods for determining compliance with each specification are incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>. Copies of the methods are available from the sources listed in the table in this paragraph:

Specification	Limit	Method Cited	Source for Obtaining Method
* * * * *			
(6) Acid Value	Not more than 4.0	"Acid Value," Appendix VII, Method I (Commercial Fatty Acids), in the Food Chemicals Codex, 7th ed. (2010), p. 1220.	United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <a href="http://www.usp.org">http://www.usp.org</a> )
(7) Residue on Ignition	Not more than 0.7%	"Residue on Ignition," Appendix IIC, Method I, in the Food Chemicals Codex, 7th ed. (2010), pp. 1141-1142 (using a 1-gram sample).	Do.
(8) Residual Methanol	Not more than 10 milligrams/kilogram	Method listed in the monograph for "Sucrose Fatty Acid	Do.

Specification	Limit	Method Cited	Source for Obtaining Method
		Esters” in the Food Chemicals Codex, 7th ed. (2010), pp. 998-1000.	
(9) Residual Dimethyl Sulfoxide	Not more than 2.0 milligrams/kilogram	Do.	Do.
(10) Residual Isobutyl Alcohol	Not more than 10 milligrams/kilogram	Do.	Do.
(11) Lead	Not more than 1.0 milligram/kilogram	“Atomic Absorption Spectrophotometric Graphite Furnace Method,” Method I in the Food Chemicals Codex, 7th ed. (2010), p. 1154-1155	Do.

\* \* \* \* \*

#### PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

20. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

21. Amend § 173.160 by revising paragraph (d) to read as follows:

§ 173.160 Candida guilliermondii.

\* \* \* \* \*

(d) The additive is so used that the citric acid produced conforms to the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 226-227, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-

796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to:

<http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

22. Amend § 173.165 by removing the first three sentences in paragraph (d) and adding five sentences in their place to read as follows:

§ 173.165 Candida lipolytica.

\* \* \* \* \*

(d) The additive is so used that the citric acid produced conforms to the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 226-227, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to:

<http://www.archives.gov/federal-register/cfr/ibr-locations.html>. \* \* \*

\* \* \* \* \*

23. Amend § 173.228 by revising paragraph (a) and removing footnote 1 to read as follows:

§ 173.228 Ethyl acetate.

\* \* \* \* \*



(a) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 343-344, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

24. Amend § 173.280 by revising paragraph (c) to read as follows:

§ 173.280 Solvent extraction process for citric acid.

\* \* \* \* \*

(c) The citric acid so produced meets the polynuclear aromatic hydrocarbon specifications of § 173.165 and the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 226-227, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

25. Amend § 173.310 in the table in paragraph (c) by revising the entries for “Acrylic acid/2-acrylamido-2-methyl propane sulfonic acid copolymer”, “Sodium carboxymethylcellulose”, and “Sorbitol anhydride esters” and add paragraph (f) to read as follows:

§ 173.310 Boiler water additives.

\* \* \* \* \*

(c) List of substances:

Substances	Limitations
* * * * *	
Acrylic acid/2-acrylamido-2-methyl propane sulfonic acid copolymer having a minimum weight average molecular weight of 9,900 and a minimum number average molecular weight of 5,700 as determined by a method entitled "Determination of Weight Average and Number Average Molecular Weight of 60/40 AA/AMPS"	Total not to exceed 20 parts per million (active) in boiler feedwater.
* * * * *	
Sodium carboxymethylcellulose	Contains not less than 95 percent sodium carboxymethylcellulose on a dry-weight basis, with maximum substitution of 0.9 carboxymethylcellulose groups per anhydroglucose unit, and with a minimum viscosity of 15 centipoises for 2 percent by weight aqueous solution at 25 °C; by the "Viscosity of Cellulose Gum" method prescribed in the Food Chemicals Codex, pp. 1128-1129.
* * * * *	
Sorbitol anhydride esters: A mixture consisting of sorbitan monostearate as defined in § 172. 842 of this chapter; polysorbate 60 ((polyoxyethylene (20) sorbitan monostearate)) as defined in § 172.836 of this chapter; and polysorbate 20 ((polyoxyethylene (20) sorbitan monolaurate)), meeting the specifications of the Food Chemicals Codex, pp. 825-827.	The mixture is used as an anticorrosive agent in steam boiler distribution systems, with each component not to exceed 15 milligrams per kilogram in the steam.
* * * * *	

\* \* \* \* \*

(f) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of

this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(1) FDA Main Library, 10903 New Hampshire Ave., Silver Spring, MD 20993:

(i) “Determination of Weight Average and Number Average Molecular Weight of 60/40 AA/AMPS” (October 23, 1987).

(ii) [Reserved].

(2) United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>):

(i) Food Chemicals Codex, 7th ed. (2010), pp. 1128-1129.

(ii) Food Chemicals Codex, 7th ed. (2010), pp. 825-827.

26. Amend § 173.368 by revising paragraph (c) to read as follows:

§ 173.368 Ozone.

\* \* \* \* \*

(c) The additive meets the specifications for ozone in the Food Chemicals Codex, 7th ed. (2010), pp. 754-755, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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PART 178--INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND  
SANITIZERS

27. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

28. Amend § 178.1005 by revising paragraph (c) to read as follows:

§ 178.1005 Hydrogen peroxide solution.

\* \* \* \* \*

(c) Specifications. Hydrogen peroxide solution shall meet the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 496-497, which is incorporated by reference. Hydrogen peroxide solution shall also meet the specifications for “Acidity,” “Chloride,” and “Other requirements” for Hydrogen Peroxide Concentrate in the United States Pharmacopeia 36th Revision (2013), pp. 3848-3849, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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PART 180--FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON  
AN INTERIM BASIS PENDING ADDITIONAL STUDY

29. The authority citation for 21 CFR part 180 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371; 42 U.S.C. 241.

30. Amend § 180.37 by revising paragraph (b) to read as follows:

§ 180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

\* \* \* \* \*

(b) The food additives meet the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 52-54, 153-154, 898-899, 961-962, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to:

<http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

\* \* \* \* \*

Dated: November 21, 2013.

Susan M. Bernard,

Director,  
Office of Regulations, Policy and Social Sciences,  
Center for Food Safety and Applied Nutrition.

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